

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
Civil No. _____**

UNITED STATES OF AMERICA,)
)
Plaintiff,)
)
v.) JURY TRIAL DEMANDED
)
)
VISION QUEST, INCORPORATED,)
)
Defendant.)

UNITED STATES OF AMERICA'S COMPLAINT

The United States of America (“United States” or “the government”), on behalf of the United States Department of Health and Human Services (“HHS”), brings this action against Defendant Vision Quest, Incorporated (“VQ”) under the False Claims Act, 31 U.S.C. §§ 3729–3733, and federal common law.

I. INTRODUCTION

1. VQ is a manufacturer of durable medical equipment, including knee braces. It utilizes sales representatives, including independent sales representatives, to sell its products.
2. One of VQ’s independent sales representatives was a company called Results Laboratories LLC (“Results”), which was owned and controlled by Mathias Berry (“Berry”).

3. Berry, a non-practicing chiropractor, developed a practice model for a network of medical clinics specializing in non-surgical treatments for osteoarthritis. He recruited chiropractors across the country to open and run the clinics. They called these clinics the Osteo Relief Institutes (“ORIs” or “ORI Clinics”).

4. Beginning in 2011 and continuing through 2018, VQ paid Berry and his company, Results, kickbacks in the form of commission payments that ranged from 20–35 percent of VQ’s net revenue on each knee brace ordered by the ORI Clinics.

5. The ORI Clinics were unaware of this arrangement. Berry and Anti-Gravity Effects, LLC (“AGE”) simultaneously acted as a management company for the ORIs, directing their purchasing decisions and taking approximately 10% of their overall revenue, including brace sales.

6. Operating under the direction of Berry and his companies, the ORI Clinics submitted claims for millions of dollars in Medicare reimbursements, including between 2013 and 2018. Berry trained the ORIs to maximize profits, focusing primarily on revenue from Medicare beneficiaries. The ORIs focused much of their efforts on providing as many knee braces as they could. They placed particular emphasis on providing, and billing Medicare for, the most profitable braces, irrespective of patient need.

7. VQ profited handsomely from the arrangement. By paying Berry and Results kickbacks in the form of sales commissions, VQ was able to establish itself as the exclusive brace supplier for 10-12 ORIs annually between 2011 and 2018. VQ understood that Berry was in a position to tell the ORIs which braces to order. This locked in millions of dollars in annual brace sales for VQ.

8. VQ and Berry also offered special treatment to Berry's business partner, David Podell, who originated the ORI scheme with Berry and also operated two ORI Clinics. Berry and his companies initially gave Podell a 20% "back end sales fee" on every VQ knee brace Podell ordered. Podell later switched to a VQ competitor, and in 2016 VQ wanted him to start ordering VQ braces again. But VQ did not want to report the lower price to Medicare, and VQ therefore provided Podell with "free" knee braces as a "rebate."

9. Throughout the arrangement, VQ knew that it is wrongful and illegal to pay a sales commission to an independent contractor in a position to refer federal program business to VQ. VQ was also aware that it was wrongful to pay Berry and Results to recommend or arrange for the ORI Clinics' purchase of knee braces from VQ for the ORI Clinics' Medicare patients in light of Berry's dual role.

10. VQ and Berry went to great lengths to conceal the nature of their relationship, further demonstrating VQ's knowledge of the scheme's illegality. Berry and his lead executive, Kate Ross ("Ross"), strictly prohibited VQ and the ORI Clinics from talking to one another. VQ agreed not to contact the ORIs directly. The purpose of restricting communication between VQ and the ORIs was to conceal Berry's VQ sales commissions from the ORI Clinics.

11. VQ also concealed the true nature of its arrangement with Results and Berry in its formal contracts. First it included a false statement in Results' sales representative agreement with VQ indicating that Berry had no control over the ORIs, and no financial interest in them. Then in 2015, VQ agreed to pay Berry and Results higher commissions for an arrangement whereby the ORI Clinics would purchase braces exclusively from VQ.

Lynn Beaumarchais, VQ's primary contact with Berry, agreed to do so but told Berry that VQ's lawyer advised them to break the agreement into two separate documents so that it would not look like a kickback.

12. By the conduct alleged in this Introduction and in more detail below, VQ knowingly caused the ORI Clinics to submit false claims to Medicare from January 1, 2013 through December 31, 2018. The claims resulted from VQ's fraudulent kickback scheme. Throughout the relevant time period, Medicare paid for most of the knee braces that VQ sold to the ORI Clinics, and Berry and Results specifically targeted Medicare beneficiaries through various techniques. The kickback scheme resulted in substantial costs to the Medicare program, diverting tens of millions of dollars towards items tainted by violations of the Anti-Kickback Statute.

13. VQ's illicit arrangement with Berry and Results demonstrates several hallmarks of the harms that the AKS is designed to prevent. It fostered overutilization and caused patients to receive products based on kickbacks even when a lower cost and higher quality competitive product may have been available in the marketplace. And Medicare paid for the products.

II. PARTIES AND BACKGROUND

14. Plaintiff the United States brings this action on behalf of HHS, including the HHS component the Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicare program.

15. Defendant VQ is a corporation organized under California state law, with a principal place of business in Irvine, California. VQ manufactures knee braces and other

products intended to treat conditions such as osteoarthritis. It conducts business across the country, and conducted a substantial amount of business in Minnesota during the relevant time period, including with the ORI Clinic based in Minnesota.

16. AGE licensed the ORI system to the ORI Clinics and in return collected a percentage of the ORI Clinics' revenue. Berry controlled the operations of AGE throughout the relevant time period.

17. ORI Clinics purchased knee braces and injection supplies and obtained other services through Results. Results was wholly owned and controlled by Berry until August 2015, when ownership was transferred to Northwest MedTech, Inc. Berry controlled Northwest MedTech, Inc. and served as its majority owner, and he retained operational control of Results.

III. JURISDICTION AND VENUE

18. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1345 because this action is brought by the United States as a Plaintiff pursuant to the False Claims Act.

19. This Court may exercise personal jurisdiction over VQ pursuant to 31 U.S.C. § 3732(a) because VQ transacts business in the District of Minnesota, and it did so during the relevant time period.

20. Venue is proper in the District of Minnesota under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because VQ transacts business in this District and did so during the relevant time period, and because a substantial part of the events or omissions giving rise to the claim occurred in Minnesota.

21. Until August 2015, one of the ORI Clinics was based in Minnesota, and VQ conducted a significant amount of business with that entity as part of its scheme. That entity, Minnesota Arthritis Center (“MAC”), ordered braces and other products from VQ through its sales representative, Results and paid license fees to AGE. After MAC’s relationship with Berry was terminated in 2015, MAC continued to order braces through VQ.

IV. STATUTE OF LIMITATIONS

22. VQ executed tolling agreements with the United States that tolled the running of the statute of limitations from June 11, 2018 through May 29, 2020.

23. The relevant time period for this case is January 1, 2013 through December 31, 2018.

24. All of the claims in this complaint are timely under 31 U.S.C. § 3731(b)(1).

V. LEGAL BACKGROUND

A. The False Claims Act

25. The False Claims Act (“FCA”), 31 U.S.C. § 3729 *et seq.*, was enacted to protect the Federal Treasury. It provides, in pertinent part, that:

any person who:

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

...

is liable to the United States Government for a civil penalty . . . , plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a).

26. The FCA defines “knowingly” as “actual knowledge,” “reckless disregard,” or “deliberate ignorance” of truth or falsity, and expressly “require[s] no proof of specific intent to defraud.” *Id.* § 3729(b)(1).

27. The term “claim” under the FCA means “any request or demand, whether under a contract or otherwise, for money or property” from the United States. *Id.* § 3729(b)(2).

28. A false claim is “material” under the FCA if it has a “natural tendency to influence, or is capable of influencing,” the government’s payment decision. *Id.* § 3729(b)(4).

B. The Anti-Kickback Statute

29. The Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b(b), was enacted out of congressional concern that inducements can lead to corruption of medical decision-making, overutilization of services and supplies, goods and services that are of poor quality or harmful, unfair competition, and increased costs to Federal health care programs. To protect the integrity of Federal health care programs from these difficult-to-detect harms, Congress enacted a broad prohibition against the payment of kickbacks in any form.

30. The AKS prohibits any person or entity from knowingly and willfully offering, paying, soliciting, or receiving any remuneration, directly or indirectly, to induce or reward a person for, *inter alia*, purchasing, ordering, arranging for, or recommending

the purchase or ordering of any goods or services for which payment may be made, in whole or in part, under a federal health program, including Medicare. 42 U.S.C. § 1320a-7b(b)(1),(2).

31. In addition to criminal penalties, violations of the AKS can subject the perpetrator to exclusion from participation in federal health care programs and civil monetary penalties. *Id.* § 1320a-7(a); 1320a-7(b)(7).

32. In the Patient Protection and Affordable Care Act (“PPACA”), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119, 757 (2010) (codified at 42 U.S.C. § 1320a-7b(g)), Congress made clear that a claim that violates the AKS is a false or fraudulent claim under the FCA. *See* 42 U.S.C. § 1320a-7b(g). According to PPACA’s legislative history, this amendment to the AKS was intended to clarify “that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil actions under the False Claims Act, even when the claims are not submitted directly by the wrongdoers themselves.” 155 Cong. Rec. S10852 (Oct. 28, 2009) (statement of Sen. Kaufman).

33. The United States Department of Health and Human Services Office of Inspector General (HHS-OIG) has promulgated “safe harbor” regulations that identify payment practices that are not subject to the AKS because such practices run a lesser risk of resulting in fraud or abuse. *See* 42 C.F.R. § 1001.952. Safe harbor protection is afforded only to those arrangements that meet all of the specific conditions set forth in the safe harbor. VQ’s conduct in this matter does not comply with any safe harbors.

C. The Medicare Program

34. Title XVIII of the Social Security Act of 1965, 42 U.S.C. § 1395 et seq., established the Health Insurance for the Aged and Disabled Program to pay for the costs of certain health care services. Commonly known as the “Medicare Program” or simply “Medicare,” the program is federally funded and provides health care services to persons 65 years of age and above and to certain disabled persons.

35. The United States administers the Medicare Program through HHS. HHS delegates direct responsibility for administration of the Medicare Program to its component agency, CMS.

36. The Medicare Program has several parts, including Part B, which authorizes payment for medical and other health services, including physician services, and prescription drugs that are provided incident to a physician’s service and cannot usually be self-administered. *See* 42 U.S.C. § 1395k.

37. Medicare covers only reasonable and necessary medical services. *See* 42 U.S.C. § 1395y(a)(1)(A) (providing that no payment shall be made under Part B for items or services “that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member”); 42 U.S.C. § 1320c-5(a)(1) (requiring providers to assure that they provide services only when and to the extent medically necessary); *see also* 42 C.F.R. § 411.15(k)(1). The requirement that services be reasonable and necessary is central to the government’s reimbursement decision under Medicare for Part B services because it strikes at the essence of the government’s bargain with healthcare providers.

38. Healthcare providers that wish to submit claims for Medicare reimbursement must enroll in the Medicare program. As a part of that enrollment process, the provider must certify its compliance with Medicare laws, regulations, and program instructions and conditions. *See 42 C.F.R. § 424.510.*

39. In particular, a provider must sign a Medicare Provider Enrollment Agreement (CMS Form 855) to participate in the Medicare program. The Provider Enrollment Agreement states, “I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier’s compliance with all applicable conditions of participation in Medicare.” By signing the form, the applicant attests to having read and understood all applicable Medicare laws, regulations, and program instructions.

40. To obtain Medicare and Medicaid reimbursement for certain outpatient items or services, providers and suppliers submit a claim form known as the CMS 1500 form (“CMS 1500”) or its electronic equivalent, the 837P format. 42 C.F.R. § 424.32.

41. Among the information the provider or supplier includes on a CMS 1500 or 837P are certain five-digit codes, including Current Procedural Terminology Codes (“CPT codes”) and Healthcare Common Procedure Coding System (“HCPCS”) Level II codes, that identify the services rendered and for which reimbursement is sought, and the unique

billing identification number of the “rendering provider” and the “referring provider or other source.” The Medicare statute requires that each request for payment or bill submitted for an item or service payable under Medicare Part B include the name and unique physician identification number for the referring physician. 42 U.S.C. § 1395l(q)(1).

42. When submitting claims to Medicare, providers certify on the CMS 1500, *inter alia*, that (a) the services rendered are medically indicated and necessary for the health of the patient; (b) the information on the claim form is “true, accurate, and complete”; and (c) the provider understands that “payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of material fact, may be prosecuted under applicable Federal and State laws.” Providers further certify that their claims comply “with all applicable Medicare . . . laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as the Stark Law).” CMS 1500 also requires providers to acknowledge that: “Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties.”

43. Similarly, when enrolling to submit claims electronically, providers certify that they will submit claims that are “accurate, complete, and truthful.” <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS10164B.pdf> (last visited May 31, 2019).

44. In submitting Medicare claim forms, providers must certify that the information included on the form presents an accurate description of the services rendered and that the services were medically necessary. A provider's certification that the services were medically necessary is a condition of payment of the claim. 42 C.F.R. § 424.24.

45. Compliance with the AKS is a condition of payment under federal health care programs, and providers participating in the Medicare and Medicaid programs must agree to comply with the AKS and certify such compliance.

46. From January 1, 2013 through December 31, 2018, VQ caused the ORI Clinics to submit claims to CMS, through various Medicare contractors, for knee braces tainted by illegal kickbacks.

VI. VQ CAUSED THE ORI CLINICS TO BILL MEDICARE FOR EXPENSIVE KNEE BRACES THAT WERE TAINTED BY KICKBACKS AND THAT MANY PATIENTS DID NOT NEED

47. VQ provided Berry, through his companies Results and AGE, with a sales commission on every VQ knee brace the ORI Clinics purchased. While VQ provided these commissions, it knew that Berry controlled the referrals from the ORI Clinics and was directing them to order knee braces from VQ. VQ went to great lengths to conceal the relationship from the ORI Clinics.

48. The ORI Clinics were part of a brand started by Berry that specialized in treatment of osteoarthritis of the knee through three primary modalities: (1) viscosupplementation, (2) knee braces, and (3) physical therapy. Viscosupplementation is a treatment therapy for osteoarthritis in which a doctor injects synthetic hyaluronic acid

into a patient's joint to supplement the natural elastic and viscous properties of synovial joint fluid.

49. VQ's kickback scheme incentivized Berry and Ross to push the ORIs to order unnecessary knee braces, including expensive custom-fabricated knee braces for patients who did not need braces or could have used less expensive braces or orthotics. VQ encouraged this behavior, in part by setting sales targets and letting Berry and Ross know when sales were falling short of expectations.

A. VQ's Secret Kickbacks to Results

50. VQ paid Results a commission of between 20-35% on every brace that an ORI Clinic purchased.

51. AGE received a share of the Medicare reimbursement for the false claims seeking reimbursement for knee braces through its license agreements with the ORI Clinics. It also participated in the scheme as the management company for the ORIs, directing them provide as many knee braces as possible.

52. VQ charged the clinics prices that were considerably higher than VQ's competitors, and higher than VQ would have been willing to charge the ORI Clinics if it had not been paying kickbacks to Berry. Indeed, when former ORI Clinics terminated their arrangement with AGE and continued to order braces from VQ, VQ gave them better prices.

53. Beginning in December 2015, VQ agreed to give a much better deal, as compared with the other ORIs, to clinics operated by Berry's business partner David Podell. Podell had moved his business away from VQ because comparable braces from a

VQ competitor cost far less than what VQ and Results were charging the ORI Clinics. VQ beat the price offered by the competitor, but disguised the arrangement from Medicare and the other ORIs by giving Podell's clinics free braces in conjunction with his orders rather than lowering the per-brace price.

54. VQ was aware that throughout the relevant time period, Berry directed the ORI Clinics to order braces exclusively from VQ. In 2015, VQ formalized an exclusive relationship that prohibited Berry and Results from selling knee braces that competed with VQ.

55. VQ was aware that its arrangement with Results was wrongful and illegal. It was aware that Berry was controlling the brace referrals from the ORI Clinics while receiving commissions on the braces provided to Medicare beneficiaries.

56. VQ took steps to disguise the arrangement. The contracts between VQ and Results intentionally misstated Berry's relationship with the ORI Clinics to make them appear consistent with the AKS. And when VQ and Results formalized the exclusive arrangement in 2015, they memorialized the agreement in two separate documents so that it would appear less like a kickback.

57. The ORI Clinic group was one of VQ's largest customers.

58. Berry and Ross made very clear to both VQ and the ORI Clinics that they were not permitted to contact each other, and that all communications must be routed through Berry and Ross. They imposed this restriction to prevent the ORI Clinics from discovering that Berry and Results were receiving a commission on the brace orders.

59. VQ understood that preventing communications between VQ and the ORI Clinics would have a negative impact on the quality of custom-fabricated braces provided to beneficiaries. VQ could not discuss the braces with the ORIs, and therefore could not provide instructions to the ORIs or correct poor-quality photos that were used to manufacture the custom braces. The company was willing to accept that tradeoff in order to continue to receive sales from Results and the ORIs.

60. The powerful incentives created by the kickback arrangement led Berry and his companies to encourage the clinics to over-prescribe knee braces. The more knee braces and other VQ products the ORI Clinics purchased, and the more VQ charged, the more Results and Berry received in commissions.

61. Numerous chiropractors ultimately signed up for the ORI program, entered into licensing agreements with AGE, and operated ORI Clinics, including the following:

- A. Jeff Lavell and Joe Biernat, chiropractors licensed in Minnesota, who operated an ORI Clinic in Maplewood;
- B. Kevin Barton, a chiropractor licensed in Texas, who operated ORI Clinics in San Antonio and Austin;
- C. Cassidy Boelk, a chiropractor licensed in California, who operated an ORI Clinic in San Diego;
- D. Igal Dubov, a chiropractor licensed in New Jersey, who operated an ORI Clinic in Wall Township;
- E. Andrew Keith, a chiropractor licensed in California, who operated an ORI Clinic in West Covina;

- F. Jeffrey Keller, a chiropractor licensed in Colorado, who operated ORI Clinics in Colorado Springs and Denver;
- G. Stephen Lembo, a chiropractor licensed in New York, who operated an ORI Clinic in Smithtown;
- H. Brett MacKenzie, a chiropractor licensed in Texas, who operated an ORI Clinic in Dallas, along with his father, David MacKenzie;
- I. Scott MacKenzie, a chiropractor licensed in Arizona (and Brett's brother), who operated an ORI Clinic in Phoenix;
- J. Anthony Scatena, a chiropractor licensed in Kentucky, who operated ORI Clinics located in Lexington and Louisville;
- K. Doug Simper, a chiropractor licensed in Illinois, who operated an ORI Clinic in Elmhurst; and
- L. David Podell, a chiropractor licensed in New Jersey, who operated clinics in Edgewater, New Jersey and in New York City under the ORI brand.

B. VQ Encouraged Berry and Ross to Pressure the ORI Clinics to Order More Braces to Meet VQ's Sales Targets and Increase Results' Sales Commissions

62. Beaumarchais, VQ's primary contact with Berry and Results, informed Berry and Results of their sales targets and encouraged them to meet those targets. When the brace sales to the ORI Clinics were below those targets, Beaumarchais encouraged Berry and Results to take action to meet them.

63. Berry and Ross, in turn, urged the ORI chiropractors to increase brace sales (and correspondingly Results' commissions from VQ). In particular, Berry pushed the expensive VQ custom-fabricated knee braces, without regard for patient need.

64. On multiple occasions, Beaumarchais contacted Berry and Ross to let them know that they were not on track to meet their monthly sales numbers. She understood that they would take action to address the issue.

65. For example, on October 1, 2013, Beaumarchais sent Berry an email, indicating that the September numbers are "not close to where you thought you would be."

66. The very next week, Berry pressured several ORI chiropractors to increase the number of braces offered to patients. On October 6, 2013, Berry told the ORI Colorado Springs chiropractors that they "really need to figure out the braces." Without having met, seen, or evaluated any patients, he continued, "we only have 21 braces and 36 arthrograms ... [t]hat needs to be at least 28 based on that. We are 7 shy MINIMUM ... We need to keep that number up. Mission Critical." Writing later in the chain, Berry instructed, "[your] number one job is to get braces out[.] and you know when you do an xray that person is going to need a brace so you can be ready." On October 8, 2013, a clinic chiropractor at the ORI Colorado Springs clinic wrote back to Berry, "I am trying to use the 'entrepreneurial spirit' you mentioned to improve the brace numbers."

67. Also on October 6, 2013, Berry told the ORI Dallas chiropractor to "get those braces back up. You have 61 Arthrograms. That's at least 50 braces."

68. That same day, Berry told Igal Dubov in New Jersey, "Hey you REALLY NEED TO WORK ON THIS THIS WEEK[.] You did 60 Arthrograms[.] WORST case

you should be at 48 braces. You did 31[.] That's off by minimum of 17[.]” Telling Dubov that this lost revenue is a “difference of about 12k or 50k a month,” Berry continued, “That's like almost all your empl[o]yee costs paid, or most of your marketing, or a new BMW every month … it's worth it!!!”

69. The next week, Berry wrote a similar email to the Minnesota ORI. Berry complained that the opportunity cost of not providing enough braces equated to “5-10 grand last week…20-40K a month [...] 240 to 480 a year.” Joe Biernat, one of the chiropractors who controlled the Minnesota operation, responded, “We are pushing out as many as we can. We would like to do more as well.” Berry then asked to speak with him to see what they could do to “improve the touch points.”

70. In November, after seeing ORI’s sales go up dramatically, Beaumarchais wrote, “WOW … did you just overload their shelves....” Results’ brace sales to the ORIs increased from just under \$500,000 for September 2013 to just over \$700,000 for October 2013. VQ paid Results \$125,000 in commissions for that month alone, a 25% increase from the previous month.

71. In July 2017, Beaumarchais emailed Berry and Ross to express concern that the brace numbers were lower than she expected. She wrote, “I am copying Kate too as I know she is very instrumental in driving the order . . . I know Kate always pushes braces!!!!”

72. The financial incentives created by VQ’s illicit kickback arrangement led Berry to push brace sales on other occasions as well.

73. For example, when the San Antonio clinic chiropractor told Berry that he already had too many braces on his shelves and did not want to order more, Berry responded that “[t]here shouldn’t be any braces there at all – that’s like 30k a month minimum lost[.] … The braces [stacking] up is the only thing [I] have to know whether they are handing them out and seems to be the only reason you know too.... At this point short of a dog shock collar that shocks the [expletive] out of them if a new patient walks out without a brace when appropriate, [I’m] at a loss.”

74. Berry told the Minnesota ORI Clinic chiropractor in 2013 that he should “make sure it’s explained when [taking] the pictures that once the pictures are taken they have to get the brace.”

75. Berry informed another chiropractor in 2012 that 80 percent of the patients should be “candidates for braces” and that half of those should be bilateral, meaning the patients should get two braces.

76. When the Dallas chiropractor permitted someone else to screen patients for braces, Berry informed him that the brace numbers had been way too low. Berry directed the chiropractor, “you need to do ALL of [the brace screenings] until further notice.”

77. In late-May 2014, Berry told one of the Colorado chiropractors to go through the files of the patients who were coming in the following week and plan to give all of them braces. The following day, the chiropractor in charge of increasing brace usage in the Colorado location emailed Berry to celebrate the fact the location had broken its previous record for the number of braces given out in a single day. Berry complimented his “great great work.”

78. Ross thanked the brace specialist at the San Diego location in June 2015 for doing so many custom braces.

C. VQ Was Aware that Berry Controlled the ORI Clinics

79. VQ was aware that Berry exerted considerable control over the ORI Clinics and largely controlled their operations.

80. In 2016, when VQ was having trouble collecting money from the ORI Clinics, another VQ executive suggested that VQ should reach out to the ORI Clinics directly. Beaumarchais made clear to him that Berry controlled the whole operation, and that circumventing him could have disastrous consequences.

81. Beaumarchais informed the VQ executive:

Results Lab entity is Matt Berry, which hold these accounts (and us) captive by the services, contract and process which he controls. These shareholders for the most part play in his sandbox. He picks programs and products, services, lawyers, billers, marketing, training, and name recognition “Osteo Relief[.]” The principal shareholder [referring to the chiropractor operating each ORI Clinic] does not veer from the system often as they feel he brings value to their business and growth. Those who have chosen to explore other options have been cut off immediately.

82. Beaumarchais reiterated the strict communication restriction: “we are not allowed to contact the shareholders directly . . . I am not allowed to contact the office without permission. So to reach out to these offices for a payment plan and not arrange it through Matt could be catastrophic to us for all locations.”

83. Beaumarchais advised that “one account already uses [a VQ competitor] and only orders because Matt makes him.” If VQ angered Berry, “Matt will source the change and he more than likely will move all business away.” She indicated that the ORI

Clinics had concerns about the quality of the VQ braces, and indicated, “to believe any location is satisfied with our product and would not look elsewhere or support us if Matt tried to changed products would be naive on our part.”

84. Beaumarchais further advised, “I believe as long as the shareholders are associated with Matt these accounts [are] an all or nothing complicated entity . . . On a side note they supposedly are opening new locations. Future business ???”

D. Podell Arrangement

85. David Podell had a unique role among the chiropractors who controlled ORI Clinics. He operated ORI Clinics in New Jersey and New York. In addition, he was Berry’s business partner and received a portion of AGE’s profits, as well as a commission on the brace sales at his practice for a period of time.

86. Because Podell and Berry were partners in the original ORI scheme, Berry did not control Podell’s behavior to the same degree as the chiropractors at the other ORI Clinics. Podell learned in 2012 that one of VQ’s competitors offered a similar brace for less money than Berry and VQ were charging the ORI Clinics. In October 2012, Podell told Berry that “VQ is way too high with their prices . . .” He told Berry and Ross that VQ needed to reduce their prices considerably to be competitive with other brace manufacturers. Podell ultimately stopped ordering from VQ and began ordering from the competitor.

87. VQ was very interested in regaining Podell’s business. It knew that Podell was price-sensitive, and asked Berry to determine the price it would have to charge in order

to bring him back into the fold. Berry obtained that information from Podell and sent it to VQ.

88. Although VQ had a strong desire to regain Podell's business, it did not want to lower the actual price it charged for the braces. Beaumarchais told Berry that there were two reasons for this reluctance. She indicated that the primary reason VQ did not want to lower the price was to avoid having to report that price to Medicare, which she explained to Berry would impact VQ's future Medicare reimbursement. VQ did not want to report to the government that it was charging one of its customers a considerably lower price than it was charging other customers. VQ also did not want to lower the price it was charging the other ORI Clinics.

89. Therefore, instead of lowering its prices, VQ chose to provide Podell with free braces when he ordered braces from them. Because the price Podell had been receiving from VQ's competitor was so much lower than the price VQ and Berry were charging the ORI Clinics, VQ had to provide 11 free braces for every 20 braces Podell ordered in order to beat its competitor's overall price.

E. Concealment

90. The ORI Clinics were unaware that Berry was acting as a clandestine VQ sales representative. Forbidding direct communications between VQ and the ORIs permitted Berry to conceal the arrangement. VQ actively participated in the subterfuge.

91. Beaumarchais told fellow VQ representatives on multiple occasions that Berry and Ross strictly prohibited VQ from reaching out to the ORIs without Berry's express consent. She informed her colleagues on multiple occasions that Berry felt so

strongly about preventing these communications that if VQ contacted the ORIs directly, Berry would likely terminate the VQ relationship and take the ORIs' business elsewhere.

92. VQ was aware that acquiescing in this prohibition on contacting the ORI Clinics created quality of care issues.

93. In order to manufacture a custom-fabricated knee brace, VQ asked its customers to send photos of the patients' knees in order to manufacture a brace suited to the patient.

94. In 2013, the ORI Clinics were routinely sending pictures to VQ that were of such poor quality that they were very difficult to use.

95. In July 2013, for example, the Minnesota ORI sent pictures of two knees for a patient's bilateral order. VQ's order processing specialist realized that the pictures were obviously not from the same patient, and asked Ross to check with the Minnesota ORI and fix the pictures. Ross responded that the client had reviewed the pictures and said they looked good.

96. The VQ specialist forwarded the issue to VQ's Chief Operating Officer, Kevin Lunau, who told Beaumarchais that the VQ products are "only as good as the pattern it's made from" and that having pictures from two different patients was a problem. He told Beaumarchais that he would send a number of examples of problematic photos to Beaumarchais, and that she needed to go around Berry and contact the ORI Clinics directly to get them trained.

97. Beaumarchais responded that if VQ in fact went around Berry to contact the clinics directly and get them trained, “we can kiss the business goodbye. You need to understand at this point he will not let us train them.”

98. VQ continued to use the subpar photos without training the ORI Clinics, and the issues continued. In September 2013, one of the other ORI Clinics sent photos to VQ to make custom braces that Berry described as a “wreck” and the order processing specialist agreed were “horrible.” When the VQ order processing specialist asked Lunau how to proceed, Lunau told the specialist that she should just do the best she could with the horrible photos.

F. VQ Was Aware that Its Arrangement with Results Was Wrongful and Illegal

99. VQ knew throughout the relevant time period that the AKS prohibits offering, paying, soliciting, or receiving anything of value to induce referrals for Medicare services or items and that Medicare does not reimburse services or items tainted by kickbacks.

100. VQ’s discussions of the arrangement confirm its awareness that the arrangement was wrong, improper and illegal.

101. Under a March 1, 2011 contract, Results and Berry agreed to a sales representative agreement to VQ, as a non-employee independent contractor. Under the agreement, Berry agreed to “secure orders for VQ,” “manage the business relationship with the accounts on a daily basis,” and “act as the liaison between VQ and its accounts.”

102. Section 4.10 of the March 2011 contract provided (with emphasis in the original):

Physician Relationships. CONTRACTOR represents and warrants to VQ that it is not in a position to, cannot and does not influence or in any way affect referrals of patients to VQ or to any other providers. Both VQ and CONTRACTOR acknowledge and agree that the compensation that will be paid to CONTRACTOR under this agreement has been determined based on the fair market value of the services to be provided by CONTRACTOR and no part thereof is intended to be, and no part thereof shall be construed as, payment for a referral or payment to influence a referral. **CONTRACTOR's sole member is a licensed chiropractor: however, he no longer practices and does not provide chiropractic services to patients or have any financial, management or other interest in any other entity or person that is in a position to refer patients to VQ.**

103. The bolded and underlined representation was a blatant misrepresentation.

The “Contractor’s sole member,” Berry, in fact had a “financial, management or other interest in any other entity or person that is in a position to refer patients to VQ” through his relationship with the ORI Clinics. He was actively involved in the operation of the ORI Clinics and determined the products they would use. He also collected license fees on the ORI Clinics’ total revenue via AGE’s arrangement, which included revenue from knee braces. He also was integrally involved in bringing patients to the ORI Clinics through an advertising program he established, and was generally in a position to affect referrals of patients to VQ. In short, the Section 4.10 was materially false.

104. The VQ Agreement was amended several times but always included the language in Section 4.10 above.

105. VQ’s Compliance Plan in force throughout the relevant time period dedicated a section to the prohibition on kickbacks, titled “No kickbacks,” which restated

in full the AKS' prohibition regarding kickbacks. The next section of the Compliance Plan detailed "Specific Risk Areas" and highlighted that "Arrangements with potential referral sources are subject to heightened scrutiny given the legal and regulatory framework within which VQ Orthocare conducts business," and "Kickbacks to physicians or other potential referral sources are prohibited."

106. VQ understood that its relationship with Results and Berry had to comply with the AKS, which makes it illegal to offer, pay, solicit, or receive anything of value in return for Medicare referrals.

107. The VQ Agreement included a non-compete clause, which required Berry and Results to refrain from "engag[ing] in any 'Competitive Activities'" that included "selling, offering for sale, promoting, receiving, or soliciting orders" for competing products.

108. VQ made sure that the clause in the agreement formally excluded knee braces. In practice, however, Beaumarchais indicated that from the beginning of their arrangement, she expected Berry to exclusively sell VQ knee braces. Beaumarchais also understood that Berry exerted control over the ORI Clinics, including directing them to order VQ knee braces.

109. Berry in turn treated the agreement as exclusive, pressuring and directing the ORI Clinics to use VQ knee braces. When the ORI Clinics had concerns about the quality of the braces, Berry told VQ that he was doing what he could do to keep them ordering braces from VQ. Beaumarchais internally discussed VQ's understanding of Berry's ability to do so, as in the 2016 email exchange discussed above.

110. In 2015, Berry, Results and VQ amended their agreement to expressly make VQ the exclusive brace supplier for the ORI Clinics.

111. The amended agreement also made clear that Berry, through his entities, owned and controlled the intellectual property of the ORI Clinics.

112. Because VQ was providing a commission to an individual it knew controlled the referrals from the ORI Clinics, and the individual was agreeing to exclusively sell VQ knee braces, the agreement further formalized the illegal kickback arrangement.

113. Beaumarchais and James Knape, VQ's CEO, both discussed the potential modified arrangement with Berry. VQ made clear that it was anxious to maintain its lucrative relationship with Berry. Beaumarchais understood that the company would need to run the proposed arrangement by VQ's lawyer, but in a colorful turn of phrase, she informed Knape that she would hold the lawyer's feet to the fire while massaging Berry's feet behind the scenes.

114. After consulting with the lawyer, Kevin Keenan, Beaumarchais informed Berry that VQ would agree to the updated arrangement Berry was seeking. She indicated that Mr. Keenan broke the arrangement up into two separate agreements and structured it in a particular way because it was the only way he could structure the deal so that it did not look like a kickback.

115. An arrangement that would violate the AKS if formalized in one agreement does not become legal when memorialized in two.

116. The updated agreement in 2015 formalized Berry's role as an exclusive sales agent of VQ, gave him an even greater incentive to sell as many VQ products as possible,

and made Berry's control over the ORIs explicit within the agreements. The updated agreement maintained Results' commission percentage at 25%, but gave Results the opportunity to increase that percentage to 35% in any month that it achieved a monthly sales volume target.

117. VQ was aware of, and intended, that most of the knee braces subject to this arrangement would be reimbursed by Medicare.

118. VQ was well-versed in Medicare rules and regulations, and was aware throughout the relevant time period that most knee braces intended to treat osteoarthritis would be billed to Medicare. It is a Medicare-approved provider, and it agreed to follow Medicare's rules when it enrolled as a DME provider so that it could bill the program directly.

119. In a recent audit of VQ's direct billing, CMS' Office of the Inspector General concluded that VQ had not fully complied with Medicare requirements in connection with its billing for orthotic braces. The audit specifically concluded that VQ had billed for braces that were not medically necessary, and estimated that VQ had obtained at least \$2.5 million in payments that should not have been allowed.¹

G. Sales and Representative Claims

120. VQ successfully obtained a large volume of brace sales from the ORIs. The ORIs ordered a great deal of VQ braces, including many custom-fabricated braces,

¹ This is included for context; this Complaint does not seek to recover for VQ's direct billings to Medicare.

and submitted reimbursement claims for them to Medicare. These claims were false because they were tainted by VQ's illegal kickback scheme.

121. Between 2013 and 2018, VQ paid Results and Berry more than \$5 million in sales commissions. Over that same time period, the ORI Clinics billed Medicare for over \$18 million for knee braces alone.

122. The following are representative examples of Medicare claims:

Bene	Clinic	Brace	Date From Claim	Date Received	Date Paid	Amount Paid
Patient A	Downtown NYC	K0901, Left	11/16/16	11/18/16	11/30/16	\$654.55
	Downtown NYC	K0901, Right	11/16/16	11/18/16	11/30/16	\$654.55
Patient B	Dallas	L1843, Right	10/7/13	10/10/13	10/13/13	\$660.28
	Dallas	L1843, Left	10/7/13	10/10/13	10/13/13	\$660.28
Patient C	San Antonio	L1843, Right	10/7/13	10/9/13	10/17/13	\$660.28
	San Antonio	L1843, Left	10/7/13	10/9/13	10/17/13	\$660.28
Patient D	Los Angeles	L1843, Right	10/7/13	10/21/13	10/25/13	\$641.06
	Los Angeles	L1843, Left	10/7/13	10/21/13	10/25/13	\$641.06
Patient E	Downtown NYC	K0901, Right	8/30/16	9/2/16	9/8/16	\$654.55
	Downtown NYC	K0901, Left	8/30/16	9/2/16	9/8/16	\$654.55
Patient F	Downtown NYC	L1846, Right	5/24/16	8/31/16	9/3/16	\$942.03
	Downtown NYC	L1846, Left	5/24/16	8/31/16	9/3/16	\$942.03
Patient G	Wall Township, NJ	L1843, Right	10/8/13	10/10/13	10/18/13	\$525.81

Bene	Clinic	Brace	Date From Claim	Date Received	Date Paid	Amount Paid
	Wall Township, NJ	L1843, Left	10/8/13	10/10/13	10/18/13	\$641.05
Patient H	Minnesota	L1844, Right	10/8/13	4/9/14	4/19/14	\$1,114.72
	Minnesota	L1844, Left	10/8/13	4/9/14	4/19/14	\$1,114.72
Patient I	Colorado Springs	L1843, Right	10/8/13	10/10/13	10/13/13	\$664.01
	Colorado Springs	L1843, Left	10/8/13	10/10/13	10/13/13	\$664.01
Patient J	Colorado Springs	L1844, Right	10/26/15	3/31/16	4/3/16	\$1,259.48
	Colorado Springs	L1844, Left	10/26/15	3/31/16	4/3/16	\$1,259.48
Patient K	Kentucky	L1843, Right	10/9/13	10/30/13	11/3/13	\$660.34
	Kentucky	L1843, Left	10/9/13	10/30/13	11/3/13	\$660.34
Patient L	Colorado Springs	L1844, Right	7/11/16	6/22/17	6/29/17	\$1,254.43
	Colorado Springs	L1844, Left	7/11/16	6/22/17	6/29/17	\$1,254.43
Patient M	Downtown NYC	K0901, Right	5/5/16	8/31/16	9/3/16	\$654.55
	Downtown NYC	K0901, Left	5/5/16	8/31/16	9/3/16	\$654.55
Patient N	Wall Township, NJ	L1843, Right	10/15/13	10/17/13	10/20/13	\$660.34
	Wall Township, NJ	L1843, Left	10/15/13	10/17/13	10/20/13	\$660.34
Patient O	Minnesota	L1844, Right	2/18/15	2/19/15	3/7/15	\$1,142.76
	Minnesota	L1844, Left	2/18/15	2/19/15	3/7/15	\$1,142.76
Patient P	Dallas	L1843, Right	10/15/13	10/18/13	10/23/13	\$660.28
	Dallas	L1843, Left	10/15/13	10/18/13	10/23/13	\$660.28

Bene	Clinic	Brace	Date From Claim	Date Received	Date Paid	Amount Paid
Patient Q	Colorado Springs	L1844, Right	10/15/13	10/17/2013	10/20/13	\$1,228.58
	Colorado Springs	L1844, Left	10/15/13	10/17/13	10/20/13	\$1,228.58
Patient R	Kentucky	L1844, Right	5/23/16	5/31/16	6/8/16	\$1,168.33
	Kentucky	L1844, Left	5/23/16	5/31/16	6/8/16	\$1,168.33
Patient S	Minnesota	L1843, Left	3/25/14	3/31/14	4/6/14	\$663.36
	Minnesota	L1843, Right	3/25/14	3/31/14	4/6/14	\$663.36
Patient T	Minnesota	L1844, Right	10/5/17	10/9/17	10/12/17	\$1,146.15
Patient U	Dallas	L1844, Right	11/9/15	10/31/16	11/5/16	\$1,170.96
	Dallas	L1844, Left	11/9/15	10/31/16	11/5/16	\$1,170.96
Patient V	Dallas	L1844, Right	10/17/13	10/23/13	11/6/13	\$1,142.24
	Dallas	L1844, Left	10/17/13	10/23/13	11/6/2013	\$1,142.24
Patient W	San Diego	L1844, Right	7/6/16	7/13/16	7/21/16	\$744.80
	San Diego	L1844, Left	7/6/16	7/13/16	7/21/16	\$744.80
Patient X	Dallas	L1844, Right	3/22/16	3/6/17	3/12/17	\$1,166.29
	Dallas	L1844, Left	3/22/16	3/6/17	3/12/17	\$1,166.29
Patient Y	San Antonio	L1844, Right	8/14/17	8/16/17	8/19/17	\$1,136.80
	San Antonio	L1844, Left	8/14/17	8/16/17	8/19/17	\$1,136.80
Patient Z	San Diego	L1843, Left	1/11/18	1/16/18	1/19/18	\$666.38
Patient AA	Minnesota	L1844, Right	9/15/14	9/16/14	10/9/14	\$1,125.87
	Minnesota	L1844, Left	9/15/14	9/16/14	10/9/14	\$1,125.87
Patient BB	Minnesota	L1844, Right	6/25/13	6/28/13	7/5/13	\$1,114.72
	Minnesota	L1844, Left	6/25/13	6/28/13	7/5/13	\$1,114.72

Bene	Clinic	Brace	Date From Claim	Date Received	Date Paid	Amount Paid
Patient CC	Wall Township, NJ	L1844, Right	9/14/16	9/20/16	9/23/16	\$1,142.66
	Wall Township, NJ	L1844, Left	9/14/16	9/20/16	9/23/16	\$1,142.66

H. VQ's Conduct Was Material to Payment

123. The statutory and regulatory provisions cited in this Complaint underscore the importance that the government attaches to the requirement that Part B services and items be free from the influence of kickbacks when the government decides whether to pay claims. It is also a condition of payment that providers comply with the AKS and do not offer, solicit, or receive anything of value in exchange for recommending, arranging, or ordering services or items reimbursed by Medicare.

124. A reasonable person would know that Medicare does not pay for services and items that are tainted by illegal kickbacks.

125. VQ was aware of these conditions of payment.

126. VQ engaged in a continuous pattern of behavior that caused the government to pay for services that were tainted by illegal kickbacks. These violations were not isolated at a specific ORI clinic or with respect to a particular Medicare beneficiary. Rather, as alleged in this Complaint, Defendant's violations were systematic and pervasive over a period of years, covering numerous beneficiaries who sought treatment at the ORI Clinics. Moreover, these were not technical or *de minimis* violations, but violations of basic Medicare requirements.

127. The violations were material to the government's decision to pay claims to the ORI Clinics for knee braces that were tainted by VQ's illegal kickbacks.

128. Consistent with its statutory authority, the government routinely denies payment for Part B services and items where it determines that the services are not covered by Medicare, because the services were tainted by illegal kickbacks in violation of the AKS and/or were not reasonable and necessary.

FIRST CLAIM FOR RELIEF

***Violations of the False Claims Act, 31 U.S.C. § 3729 (a)(1)(A)
Presenting or Causing to Be Presented False or Fraudulent Claims for Payment***

129. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

130. VQ knowingly caused to be presented materially false or fraudulent claims for payment or approval in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

131. VQ knowingly caused the ORI Clinics to submit false or fraudulent claims to federal health care programs, including Medicare, for claims for knee braces that were tainted by the kickback scheme. In order to protect each patient's privacy, upon the entry of an appropriate protective order, counsel for defendant will receive a list of claims that contains additional identifiers for each claim listed above as a representative example.

132. As a result of VQ's kickbacks in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), VQ knowingly caused false and fraudulent claims for payment to be made to federal health care programs, including Medicare. Throughout the relevant

time period, compliance with the Anti-Kickback Statute was material to the Government's decision to pay health care claims. Indeed, it was a condition of payment.

133. By virtue of the false and/or fraudulent claims submitted, or caused by the Defendant to be submitted, to federal health care programs, including the Medicare program, the United States suffered damages in an amount to be determined at trial, and therefore is entitled to treble damages under the False Claims Act plus a civil penalty in the statutorily required amount for each false claim.

SECOND CLAIM FOR RELIEF

Violations of the False Claims Act, 31 U.S.C. § 3729 (a)(1)(B) Use of False Records or Statements Material to False or Fraudulent Claims

134. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

135. By virtue of the foregoing, VQ knowingly caused false records or statements to be made or used material to false Medicare claims for knee braces, in violation of 31 U.S.C. § 3729(a)(1)(B). Those included, but are not limited to, false certifications of compliance with the Anti-Kickback Statute.

136. The United States, unaware of the falsity of the records and statements made by, used, or caused to be used by VQ, approved, paid, and participated in payments made by federal health care programs for claims that would otherwise not have been approved and paid.

137. By reason of these false records or statements, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty in the statutorily required amount for each false claim.

THIRD CLAIM FOR RELIEF

Unjust Enrichment

138. The United States realleges and incorporates by reference the allegations in paragraphs 1 through 128.

139. This is a claim by the United States for recovery of monies by which Defendant has been unjustly enriched.

140. The United States paid claims submitted to Medicare, a federal health care program, in connection with the conduct and acts alleged above. Those claims violated applicable federal law and regulations, including the Anti-Kickback Statute, and Defendant received money as a result of the claims. The circumstances of Defendant's receipt of taxpayer money, whether directly or indirectly, are such that, in equity and good conscience, Defendant should not retain those payments, the amount of which is to be determined at trial.

FOURTH CLAIM FOR RELIEF

Payment by Mistake

141. The United States realleges and incorporates by reference the allegations in paragraphs 1 through 128.

142. By reason of the foregoing, the United States made and/or participated in Medicare payments in reliance on the erroneous belief that the claims did not violate with

the Anti-Kickback Statute. The erroneous belief was material to the United States' decision to make the payments. Consequently, the United States is entitled to recover the payments in an amount to be determined at trial.

RELIEF REQUESTED

WHEREFORE, the United States respectfully requests judgment against Defendant as follows:

- a) On Claims for Relief One and Two, treble damages and civil penalties in the maximum amount allowed by law;
- b) On Claims for Relief Three and Four, damages to the extent allowed by law;
- c) All costs associated with prosecuting this civil action, as provided by law;
- d) Interest on all amounts owed to the United States; and
- e) For all relief the Court deems just and proper.

Dated: November 20, 2020

Respectfully submitted,

ERICA H. MacDONALD
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s/ Chad A. Blumenfield

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